

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Volkin, David B. et al.

Serial No. 10/697,233

Filed: October 30, 2003

For: DNA VACCINE FORMULATIONS

Art Unit: 1614Examiner: Vogel, Nancy S.

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97**

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK &amp; CO., INC.

By J. Mayhew Date 23 MAY 2005

05/26/2005 EFLORES 00000010 132755 10697233  
01 FC:1806 180.00 DA

**INFORMATION DISCLOSURE STATEMENT**

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

| RELATED APPLICATION |             |            |
|---------------------|-------------|------------|
| U. S. SERIAL NUMBER | FILING DATE | MERCK CASE |
|                     |             |            |
|                     |             |            |
|                     |             |            |
|                     |             |            |
|                     |             |            |
|                     |             |            |

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☒ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

  
By: J. Mark Hand

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 36,545

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-3905

Date: May 23, 2005

|  |  |  |  |   |  |                                 |  |
|--|--|--|--|---|--|---------------------------------|--|
| FORM PTO-1449  |  | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE |  | ATTY. DOCKET NO.<br><b>19698YCC</b>       |  | SERIAL NO.<br><b>10/697,233</b> |  |
| <b>INFORMATION DISCLOSURE STATEMENT</b><br>(Use several sheets if necessary) |  |  |  | APPLICANT(S)<br><b>D.B. VOLKIN ET AL.</b> |  |                                 |  |
|  |  |  |  | FILING DATE<br><b>10/30/03</b>            |  | GROUP ART UNIT                  |  |

MAY 25 2005  
 U.S. PATENT & TRADEMARK OFFICE

| U.S. PATENT DOCUMENTS  |                 |  |                 |                 |          |                            |    |
|--|-----------------|--|-----------------|-----------------|----------|----------------------------|----|
| EXAMINER INITIAL   | DOCUMENT NUMBER | DATE   | NAME            | CLASS           | SUBCLASS | FILING DATE IF APPROPRIATE |    |
|  | 5,057,426       | 10/15/91   | Henko et al     |                 |          |                            |    |
|  | 3,915,794       | 10/28/75   | Zygraich et al. |                 |          |                            |    |
|  | 5,736,524       | 4/7/98   | Content et al.  |                 |          |                            |    |
|  | 5,521,061       | 5/28/96  | Bresser         |                 |          |                            |    |
|  | 6,004,777       | 12/21/99   | Tartaglia       |                 |          |                            |    |
|  | 5,869,306       | 2/9/99   | KumA et al.     |                 |          |                            |    |
|  | 5,985,327       | 11/16/99   | Burgoyne        |                 |          |                            |    |
|  | 5,811,406       | 9/22/98  | Szoka et al.    |                 |          |                            |    |
|  | 5,851,769       | 12/22/98   | Gray et al.     |                 |          |                            |    |
|  | 6,022,737       | 2/8/00   | Niven et al.    |                 |          |                            |    |
|  | 5,561,064       | 10/1/96  | Marquet et al.  |                 |          |                            |    |
| FOREIGN PATENT DOCUMENTS   |                 |  |                 |                 |          |                            |    |
| EXAMINER INITIAL   | DOCUMENT NUMBER | DATE   | COUNTRY         | CLASS           | SUBCLASS | TRANSLATION                |    |
|  |                 |  |                 |                 |          | YES                        | NO |
|  | WO96/39813      | 12/19/96   | PCT             |                 |          |                            |    |
|  | WO96/41873      | 12/27/96   | PCT             |                 |          |                            |    |
|  | WO93/03167      | 2/18/93  | PCT             |                 |          |                            |    |
|  | WO94/02639      | 2/3/94   | PCT             |                 |          |                            |    |
|  | WO96/20732      | 7/11/96  | PCT             |                 |          |                            |    |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)   |                 |  |                 |                 |          |                            |    |
|  | AA              | Haynes et al "Gene Gun Medicated DNA Immunization Elicits Humoral, Cytotoxic and Protective Immune Response" Vaccines 1994, pp 65-70   |                 |                 |          |                            |    |
|  | AB              | Lindahl et al. "Rate of Depurination of Native Deoxyribonucleic Acid", Biochemistry, Vol. 11, No. 19, 1972                             |                 |                 |          |                            |    |
|  | AC              | Lindahl et al. "Rate of Chain Breakage at Apurinic Sites in Double-Stranded Deoxyribonucleic Acid", Biochemistry, Vol 11, No. 19, 1972 |                 |                 |          |                            |    |
| EXAMINER   |                 |  |                 | DATE CONSIDERED |          |                            |    |
| EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant. |                 |  |                 |                 |          |                            |    |

|  |    |  |  |                                     |  |                                |  |
|--|----|--|--|-------------------------------------|--|--------------------------------|--|
| FORM PTO-1449  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE   |  | ATTY. DOCKET NO.<br><b>19698YOC</b> |  | SERIAL NO<br><b>10/697,233</b> |  |
| INFORMATION DISCLOSURE STATEMENT<br>(Use several sheets if necessary)  |    |  |  | APPLICANT(S)<br>D.B. VOLKIN ET AL.  |  |                                |  |
|  |    |  |  | FILING DATE<br><b>10/30/03</b>      |  | GROUP ART UNIT                 |  |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)   |    |  |  |                                     |  |                                |  |
|  | AD | Graf et al. "Iron-catalyzed Hydroxyl Radical Formation", The Journal of Biological Chemistry, Vol. 259, No. 6, Issue of March 25, pp 3620-3624, 1984   |  |                                     |  |                                |  |
|  | AE | Greer et al. "Studies on Depurination of DNA by Heat", J. Mol. Biol. (1962), 4, 123-141  |  |                                     |  |                                |  |
|  | AF | Freitas et al "Pentoxifylline - A Hydroxyl Radical Scavenger" Biol. Trace Elem. Trs. 47: p 307-311   |  |                                     |  |                                |  |
|  | AG | Hu et al. "Para-aminobenzoic acid scavenges reactive oxygen species and protects DNA against UV and free radical damage", J. Nutr. Biochem. 6: p 504-508   |  |                                     |  |                                |  |
|  | AH | Zinkernagel et al. 'Antiviral Immunity', Immunology Today, Vol. 18 (6), pp 258-260 (1997)  |  |                                     |  |                                |  |
|  | AI | Robinson, 'Nucleic acid vaccines: an overview'; Vaccine, Vol. 15 (8), pp 785-787, (1997)   |  |                                     |  |                                |  |
|  | AJ | Strugnell et al. 'DNA vaccines for bacterial infections', Immunol. ell Biol. Vol 75, pp 364-369, (1997)  |  |                                     |  |                                |  |
|  | AK | Chattergoon et al. 'Genetic immunization: a new era in vaccines and immune therapeutics', FASEB J. , Vol. 11, pp 753-763 (1997)  |  |                                     |  |                                |  |
|  | AL | Lang, 'Tertiary Structure of Purified DNA by Dehydration with Ethanol'; Tex. Rep. Biol. Med., Vol. 31(2), p 258 (1973)   |  |                                     |  |                                |  |
|  | AM | Peak et al. "Similar Ultraviolet Action Spectra for the Protection by Glycerol of Transforming DAN against Single-Strand Breaks and Inactivation of Biological Activity"; Rad. Res. Vol. 97, pp 570-575 (1984) |  |                                     |  |                                |  |
|  | AN | Goodman et al. 'Cloning of Hormone Genes from a Mixture of cDNA Molecules'; Methods in Enzymology, Vol 68, pp 75-90, (1979)  |  |                                     |  |                                |  |
|  | AO | Sigma Catalogue, pp 485 and 1556 (1993)  |  |                                     |  |                                |  |
|  | AP | Gennaro, Remington: Practice of; 19th Edition, (1995)  |  |                                     |  |                                |  |
| EXAMINER   |    |  |  | DATE CONSIDERED                     |  |                                |  |
| EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant. |    |  |  |                                     |  |                                |  |

**INFORMATION DISCLOSURE STATEMENT**  
(Use several sheets if necessary)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

**AQ**

Gibco BRL, Life Technologies Catalogue, (1994)

AR

Graves et al. Pharmaceutical Reserach, Vol 11 (10), Suppl. S1-S490  
(1994)

AS

Sarker et al. "Oxygen radical-induced single strand DNA... system"  
Mutations Res. Vol 337, pp 85-95 (1995)

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.